

REMARKS

In view of both the amendments under 37 CFR \$1.121(a) presented above and the following discussion, the Applicants submit that none of the claims now pending in the above-identified application is anticipated under the provisions of 35 USC \$102 or rejectable as obvious to one having ordinary skill in the art under the provisions of 35 USC \$103(a). Furthermore, Applicants also submit that all of the said pending claims now satisfy the requirements of 35 USC \$132(a), 37 CFR \$1.121(a)(6), 37 CFR \$1.75(a), 37 CFR \$1.75(c) and 35 USC \$112. Thus, Applicants believe that all of said pending claims are now in allowable form; and that the above-identified application is in condition for allowance.

If, however, the Examiner believes that there are any unresolved issues requiring adverse action (that is, non-allowability of any of the said pending claims) the Examiner is respectfully requested to contact Arthur L. Liberman at telephone number 732-291-9434 or FAX number 732-872-1305 or via E-mail at aliberman@monmouth.com so that appropriate arrangements can be made for resolving such issues as expeditiously as possible.

Status of pending claims; and relationship thereof to previously-presented claims

Previously-presented claims 56, 58, 59, 60 and 83, indicated as "withdrawn" are now indicated as having been "canceled".

Previously-presented claims 67, 69, 70, 79, 80 and 86, indicated as allowable have been retained in the case without change.

Previously-presented claim 101 objected to as being dependent on a rejected claim has been currently amended to be an independent claim.

Previously-presented rejected claims 88, 99 and 100 have been canceled without prejudice.

Previously-presented rejected claims 87 and 89-98 including objected-to claims 91 and 97 have been amended, and are each limited to include "1,4-butane diisocyanate moieties".

Newly-presented claim 102 contains all of the limitations of previously-allowed claim 78 (allowed in the Office Action of April 1, 2003, Paper No. 13 and subsequently canceled by amendment in the amendment of June 30, 2003) and contains the specific limitation "wherein the polyester component is based on a linear random copolymer".

Newly-presented claims 103-115 are (i) each dependent on claim 102 and (ii) contain the limitations of previously-presented claims 88-100, with the language of newly-presented claims 106 and 112 being altered in order to overcome the objections to claims 91 and 97 presented in

paragraph 2 on page 2 of the Office Action of October 10, 2003.

Claim Objections

In paragraph 7 on page 3 of the Office Action of October 10, 2003, previously-presented process claim 101 was objected to as being dependent on a rejected claim (that is, previously-presented claim 87). The said process claim 101 has now been amended to be an independent claim, containing the language of the preamble of previously-presented claim 87. Accordingly, it is respectfully submitted that the objection to claim 101 has been overcome and that claim 101 is allowable.

In paragraph 2 on page 2 of the Office Action of October 10, 2003, claims 91 and 97 were objected to as failing to comply with the requirements of 37 CFR §1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. In supporting this objection, the Examiner in charge of the above-identified application stated:

"Claim 91 reads on chain extenders not included in the preceding claim, and claim 97 reads on other polyols, whereas claim 87 is limited to polyester polyols. It also doesn't appear that the other polyols have support in the disclosure."

Claims 91 and 97 have been amended whereby (i) claim 91 is (a) dependent on claim 87, rather than claim 90 and (b) no longer includes the ethylene glycol-based moiety for

defining the moiety, "E", or the moiety "X" or as a reactant with 1,4-butane diisocyanate and (ii) claim 97 no longer includes in the 'soft segment' grouping, "polyester-polyether" components and the hard segments are defined as "urethane-based hard segments of uniform size. Newly-presented claims 106 and 112, discussed *infra*, contain the same claim language corrections. Support for the other diol moieties in the claims, e.g. butylene diol, hexylene diol and diethylene glycol is set forth in the specification as filed at page 3, lines 17-21 and page 5, lines 33-36 and page 6, lines 1-4. Accordingly, it is respectfully urged that the claims 91 and 97 as well as newly-presented claims 106 and 112 are not rejectable under 35 USC §112 or 37 CFR §1.75(a) and that the objections based on 37 CFR §1.75(c) have been obviated.

Rejections

(A) Rejections under 35 USC §102(b)

In paragraph 4 on page 2 of the Office Action of October 10, 2003, claims 87, 89, 94 and 97-99 were rejected as being anticipated by Quay et al., U.S. Patent 4,892,920 under 35 USC §102(b). Particularly in view of the newly-presented limitation to claim 87, wherein the diisocyanate moiety is limited to a 1,4-butane diisocyanate, it is respectfully urged that the Quay et al. reference can no longer be applied to a 35 USC §102(b) rejection. As stated in the amendment filed September 4, 2002, the polyurethane of Quay et al. is based on a cyclohexane diisocyanate; chemically different in kind,

rather than degree from the 1,4-butane diisocyanate. At column 1, lines 30-35 of Quay it is stated:

"The prepolymers using cyclohexane diisocyanates, especially trans-1,4-cyclohexane diisocyanates as the isocyanate component have suffered because cyclohexanediisocyanates are volatile and toxic thus requiring special handling procedures. The prepolymers containing unreacted trans-1,4-cyclohexanediisocyanate are difficult to process because of their high melting points and high viscosities at ambient temperatures."

One of the advantages of Quay et al is the production of a low melting prepolymer having "high temperature physical properties including high hardness and stiffness, as set forth at Col. 3, lines 15-20. Indeed, a key advantage of the Quay et al. polymer is its stability under any circumstances. Although not specifically state, the biodegradability of a urethane polymer is a property unwanted by Quay et al. If the polymer of Quay et al were biodegradable, the release of the toxic cyclohexane diisocyanate during degradation in the body on use thereof would disqualify the polymer of Quay et al as a biodegradable biomedical polyurethane. Furthermore, Quay et al describes a polyisocyanate prepolymer for polyurethane/urea elastomer synthesis, as set forth in Example 7 at Columns 8-11 of Quay et al. The prepolymer is formed by reacting a cyclohexane diisocyanate and a long chain polyol. It follows from a reading of Quay et al at Columns 6-11 that those pre-polymers are typically produced by means of a reaction of a non-degradable glycol

pre-polymer with cyclohexane diisocyanate. Quay et al does not mention or imply the existence of a biomedical grade polyurethane having the formula: $\{A-B-C-B\}_n$, wherein C denotes a diol component. Quay et al does not teach either expressly or implicitly that the uniformity of the diol components is such that the length is the same for at least 90% of the diol units. In addition to such limitation, claim 87 is now limited to the diisocyanate being solely a 1,4-butane diisocyanate moiety; and newly presented claim 102, replacing previously-presented allowed claim 78 is limited to the polyester component being based on a linear random copolyester, neither of which limitation is expressly or implicitly disclosed by Quay et al. In addition, as stated on pages 15 and 16 of the amendment of February 10, 2003, the 'diols' used by Quay et al are 'polymers' for example polytetramethylene oxide diol as set forth in Example 1, Column 6, line 20. It is well known to those having ordinary skill in the art that such a polymer does not have a uniform chain length but has a chain distribution in the large range of $\pm 20-30\%$ of its average molecular weight. Accordingly it is respectfully submitted that the Quay et al cannot be used as a basis for a rejection under 35 USC §102(b) since (i) Quay et al does not teach the synthesis of a biomedical-biodegradable polymer and (ii) Quay et al does not teach a polyurethane wherein at least 90% of the diol components have the same block length.

(B) Rejection under 35 USC §103(a)

In paragraph 6 on page 3 of the Office Action of October 10, 2003, previously-presented claims 87-100 were rejected under 35 USC §103(a) as being unpatentable over de Groot et al (New biomedical polyurethane ureas with high tear strengths) (hereinafter referred to as "de Groot-(New biomedical...)") in view of Cohn et al (U.S. Patent 5,100,992), de Groot et al ("Use of porous polyurethanes for meniscal reconstruction and meniscal prostheses") (hereinafter referred to as "de Groot (Use of porous...)") and Gogolewski et al (U.S. Patent 4,915,893) for reasons as set forth in paragraphs 9-13 of the Office Action of October 16, 2002 which are restated herein:

"De Groot-(New biomedical...) discloses polyurethanes made from caprolactone polyester, polyols and butane diisocyanate... He shows polyurethanes having a homogeneous block structure. The polyester is reacted with an excess of diisocyanate (top page 212) and the excess unreacted diisocyanate is removed to make the polyester terminated with two diisocyanates. He uses these polyurethanes for medical applications. He differs from the claims by extending the prepolymer with a diamine rather than with a diol, by not showing porous polyurethanes, by not showing the specific application of meniscal reconstruction and by not disclosing polyesters of lactic acid; 10 Cohn teaches that polyurethanes for biodegradable medical applications can be chain-extended with diamines or diols (Col. 4, lines 1-18); 11. De Groot-("Use of porous...") discloses using porous polyurethanes for meniscal reconstruction;

12. Gogolewski discloses biodegradable polyurethanes made from copolymers of lactic acid and ethylene glycol (col. 2, lines 7-9).

13. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute a diol for the diamine of de Groot-("New biomedical...") because Cohn teaches that these polyurethanes are more easily dissolved or melted for shaping medical articles (top Col. 4). It would have been obvious to make the polyurethane porous and use it for meniscal reconstruction because de Groot-("Use of Porous...") discloses this as an application for mediocal polyurethanes. It would have been obvious to use polyesters of lactic acid because Gogolewski shows this for biodegradable polyurethanes. Lactic acid is known to be biocompatible because it can be found in foods."

Claims 88, 99 and 100 have been canceled without prejudice. Particularly in view of the newly-presented amendments to claims 87 and 89-98, it is respectfully submitted that the rejection of claims 87 and 89-89 under 35 USC §103(a) has been overcome for the following reasons:

- As indicated by the Examiner in charge of the above-identified application the de Groot-(New biomedical...)reference sets forth the chain extension of the prepolymer with a diamine, e.g. 1,4-diaminobutane. Thus the de Groot (New biomedical) reference creates polyurethane ureas which are referred to at lines 1-6 on page 5 of the specification of the above-identified patent application as originally filed (PCT/NL99/00352) as follows:

"Mechanical properties of polyurethane ureas are usually even better resulting from increased crystallizability and hydrogen bonding ability of the urea moieties. These polymers, however, frequently have melting points that are close to the degradation temperature, leading to a small processing window."

Accordingly, the basic issue is whether it is obvious to modify the de Groot (New biomedical...) reference teaching in such a manner as to widen the aforementioned "processing window". More specifically, the key question is whether the teachings of one or more of the secondary references can be applied to the de Groot (new biomedical...) teaching. Basic case law requires that such teaching must indicate the reasons for replacing the amine with some other functional group in order to widen the processing window. It is precisely here that each and every secondary reference, including the Cohn secondary reference, the Gogolewski secondary reference and the de Groot (Use of porous...) secondary reference fails to rise to the standard of the application of the secondary reference to the primary reference within the context of the 35 USC §103(a) case law, to wit:

- In re Dembiczak (CAFC, 4/28/99) 50 USPQ 2nd 1614;
- Robotic Vision Systems, inc. vs. View Engineering Inc. (CAFC, 9/3/99) 51 USPQ 2nd 1948;
- Aero Industries Inc. vs. John Donovan Enterprises-Florida Inc. (D.Ct.S.Ind., 11/22/99) 53 USPQ 2nd 1547; and
- Winner International Royalty Corp. vs. Wang (CAFC, 1/27/00) 53 USPQ 2nd 1580.

- The Examiner in charge of the above-identified application indicates that it would have been obvious to one of ordinary skill in the art to substitute a diol for the diamine of de Groot (New biomedical...) because Cohn teaches that these polyurethanes are more easily dissolved or melt-processed for shaping medical articles. This is, however, not the reason to substitute the diols of the polyurethane ureas of de Groot(New biomedical...). As is specifically set forth at page 2, lines 19-29 of the above-identified application, the choice to use diol extenders yields polyurethanes with better phase separation. These polyurethanes have also been found to have better mechanical properties. Such effects of chain extension of a pre-polymer are not discussed in any of the secondary references ... including Cohn and de Groot (Use of porous...). Furthermore, these publications relate to different kinds of polymers (biodegradable in the case of applicants' invention vs. biostable in the case of the reference disclosure; 4,4'-diphenylmethyl diisocyanate-polytetramethylene adipate diol polyurethane-based resins in the case of de Groot(Use of porous...)vs. 1,4-butane diisocyanate/polyester component/diol component polyurethane-based polyurethanes in the case of the above-identified application.
- Nor do any of the secondary references provide a polymer where the chain extension is performed with a diol of the structure XYX (see claim 91 and claim 106) wherein Y is a 1,4-butane-diisocyanate-based moiety and X is an n-butylene glycol, n-hexylene glycol or diethylene glycol-based moiety. It has been determined that these structures are particularly effective to lower the

possibility of trans-esterification and have improved mechanical properties.

- No one of the secondary references teaches or infers that an implant which is the subject of the above-identified application would have satisfactory mechanical properties (such as the satisfactory compression modulus needed for a meniscus substitute). Besides the biodegradability the non-toxicity and the ease of manufacturing, additional advantages of such an implant include good adhesion qualities.

**The Newly-Presented Amendments and Claims
do not contain "New Matter"**

None of the newly-presented amendments or newly-presented claims contain subject matter which can be considered as rejectable based on new matter under 35 USC §132(a) or 37 CFR §1.121(a)(6). Basis for each amendment exists in the specification as originally filed (PCT/NL99/00352).


Conclusion

Thus, Applicants respectfully submit that none of the pending claims presently in the application is anticipated under the provisions of 35 USC §102 or is obvious to one having ordinary skill in the art under 35 USC §103(a). Furthermore Applicants respectfully submit that each of the said pending claims now fully satisfies the requirements of 35 USC §112, 35 USC §132(a), 37 CFR §1.75(a), 37 CFR §1.75(c), and 37 CFR §1.121(a)(6).

In summary, Applicants believe that each of the pending claims as set forth herein is presently in condition for allowance. Accordingly, swift passage to issue of the above-identified application is earnestly solicited.

Respectfully submitted,

January 8, 2004

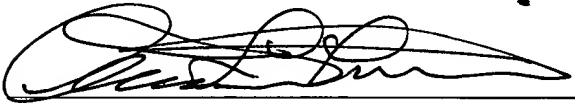


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